General

Guideline Title

Continuous glucose monitoring: an Endocrine Society clinical practice guideline.

Bibliographic Source(s)

Klonoff DC, Buckingham B, Christiansen JS, Montori VM, Tamborlane WV, Vigersky RA, Wolpert H, Endocrine Society. Continuous glucose monitoring: an Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2011 Oct;96(10):2968-79. PubMed

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Definitions for the quality of the evidence (+OOO, ++OO, +++O, and ++++); the strength of the recommendation (1 or 2); and the difference between a "recommendation" and a "suggestion" are provided at the end of the "Major Recommendations" field.

Real-Time Continuous Glucose Monitoring (RT-CGM) in Adult Hospital Settings

The Task Force recommends against the use of RT-CGM alone for glucose management in the intensive care unit (ICU) or operating room until further studies provide sufficient evidence for its accuracy and safety in those settings (1 | +OOO).

RT-CGM in Children and Adolescent Outpatients

The Task Force recommends that RT-CGM with currently approved devices be used by children and adolescents with type 1 diabetes mellitus (T1DM) who have achieved glycosylated hemoglobin (HbA1c) levels below 7.0% because it will assist in maintaining target HbA1c levels while limiting the risk of hypoglycemia (1 | ++++).

The Task Force recommends RT-CGM devices be used with children and adolescents with T1DM who have HbA1c levels of at least 7.0% who are able to use these devices on a nearly daily basis (1 | +++O).

The Task Force makes no recommendations for or against the use of RT-CGM by children with T1DM who are less than 8 yr of age.

The Task Force suggests that treatment guidelines be provided to patients to allow them to safely and effectively take advantage of the information provided to them by RT-CGM (2 | +OOO).

The Task Force suggests the intermittent use of CGM systems designed for short-term retrospective analysis in pediatric patients with diabetes in

whom clinicians worry about nocturnal hypoglycemia, dawn phenomenon, and postprandial hyperglycemia; in patients with hypoglycemic unawareness; and in patients experimenting with important changes to their diabetes regimen (such as instituting new insulin or switching from multiple daily injections [MDI] to pump therapy) (2 | +OOO).

RT-CGM in Adult Outpatients

The Task Force recommends that RT-CGM devices be used by adult patients with T1DM who have HbA1c levels of at least 7.0% and who have demonstrated that they can use these devices on a nearly daily basis (1 | ++++).

The Task Force recommends that RT-CGM devices be used by adult patients with T1DM who have HbA1c levels less than 7.0% and who have demonstrated that they can use these devices on a nearly daily basis (1 | ++++).

The Task Force suggests that intermittent use of CGM systems designed for short-term retrospective analysis may be of benefit in adult patients with diabetes to detect nocturnal hypoglycemia, the dawn phenomenon, and postprandial hyperglycemia, and to assist in the management of hypoglycemic unawareness and when significant changes are made to their diabetes regimen (such as instituting new insulins or switching from MDI to pump therapy) (2 | +OOO).

Definitions:

Quality of the Evidence

+OOO Denotes very low quality evidence

++OO Denotes low quality evidence

+++O Denotes moderate quality evidence

++++ Denotes high quality evidence

Strength of Recommendation

1 - Indicates a strong recommendation and is associated with the phrase "The Task Force recommends."

2 - Denotes a weak recommendation and is associated with the phrase "The Task Force suggests."

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Type 1 diabetes mellitus (T1DM)
- Type 2 diabetes mellitus (T2DM)

Guideline Category

Assessment of Therapeutic Effectiveness

Management

Clinical Specialty

Endocrinology

Family Practice

Internal Medicine

Pediatrics

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To formulate practice guidelines for determining settings where patients are most likely to benefit from the use of continuous glucose monitoring (CGM), specifically:

- Real-time CGM in adult hospital settings
- Real-time CGM in children and adolescent outpatients
- Real-time CGM in adult outpatients

Target Population

Adult and pediatric patients with type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM)

Interventions and Practices Considered

1. Real-time continuous glucose monitoring (RT-CGM) alone for glucose management in adults in the intensive care unit or the operating room (considered but recommended against)
2. RT-CGM based on hemoglobin A1c (HbA1c) levels
3. Provision of treatment guidelines to patients
4. Intermittent use of CGM systems in selected adult and pediatric patients
5. RT-CGM for children under 8 years of age (considered but no recommendations made for or against)

Major Outcomes Considered

- Hemoglobin A1C (HbA1C) levels
- Time hyperglycemic or hypoglycemic
- Incidence of severe hyperglycemia and hypoglycemia
- Incidence of nocturnal hypoglycemia
- Emergency medical service utilization for extremes of glycemia
- Accuracy of glucose monitoring devices
- Efficacy and safety of continuous glucose monitoring (CGM) devices versus self-monitoring blood glucose (SMBG)
- Patient satisfaction and feasibility
- Quality of life

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Eligibility Criteria

The Task Force included randomized controlled trials (RCTs) of adults and children with type 1 diabetes mellitus (T1DM) or type 2 diabetes mellitus (T2DM) in the outpatient setting. Literature search did not discriminate between different types of continuous glucose monitoring (CGM); both real-time and non-real-time CGM devices were included. The control groups needed to utilize self-monitored blood glucose (SMBG). The Task Force included RCTs regardless of their publication status, language, size, or primary objective. The Task Force excluded trials that did not have sufficient follow-up (8 weeks), were conducted in inpatient settings, had different methods of insulin delivery between the intervention and comparison arms, and primarily studied pregnant subjects.

Study Identification

An expert reference librarian designed and conducted the electronic search strategy with input from study investigators with expertise in conducting systematic reviews. To identify eligible studies, the Task Force searched electronic databases (MEDLINE, EMBASE, Cochrane CENTRAL, Web of Science, and Scopus) from 1996 to November 15, 2010. A combination of medical subject headings and text words were utilized. The detailed search strategy is available from the corresponding author of the original guideline document.

Assessment of Study Eligibility

Pairs of reviewers independently screened all abstracts and titles and selected potentially eligible studies for full-text assessment. The process was repeated in duplicate for full-text review. Disagreements were resolved by consensus or arbitration. Kappa for study selection was 0.80.

Search Results

See Table 1 and Table 2 and discussion in the companion document (see the "Availability of Companion Documents" field) for information on the characteristics and methodological quality of the 19 trials that enrolled 1,801 patients.

Number of Source Documents

A total of 990 references were screened as abstracts and 150 of them were deemed potentially eligible. Full-text review of these 150 references resulted in exclusion of 131 references (18 were not original research reports, 113 were nonrandomized). 19 studies were included.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of the Evidence

+OOO Denotes very low quality evidence

++OO Denotes low quality evidence

+++O Denotes moderate quality evidence

++++ Denotes high quality evidence

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

To synthesize evidence, the Task Force undertook a systematic review and meta-analysis of randomized controlled trials (RCTs) to evaluate the efficacy and safety of continuous glucose monitoring (CGM) compared to self-monitored blood glucose (SMBG) with regards to improving glycemic control and reducing hypoglycemia in both adult and pediatric populations with type 1 and type 2 diabetes mellitus (T1DM and T2DM).

Data Collection

Working in duplicate, a standardized form was used to extract data on study characteristics: description of participants, age, gender, number of patients involved, type of CGM, duration and frequency of use, and type of SMBG used. The Task Force also extracted outcomes of interest: hemoglobin A1c (HbA1c), time hyperglycemic and hypoglycemic, incidence of severe hyperglycemia and hypoglycemia, incidence of nocturnal hypoglycemia, emergency medical service utilization for extremes of glycemia, and patient satisfaction of CGM. Reviewers also appraised the methodological quality of eligible RCTs, considering adequacy of allocation concealment, blinding of patients, health care providers, data collectors and outcome assessors, if an RCT was stopped early, and the extent of loss to follow-up (i.e., proportion of patients in whom the investigators were unable to ascertain outcomes). For each of these variables, the Task Force used results reported in the original RCTs, thus accepting the authors' definitions of these terms. When needed, the Task Force contacted authors of the studies included by email to obtain missing data or confirm extracted data.

Statistical Analysis

The Task Force estimated the effect of CGM from each study with 95% confidence interval (CI) using the weighted mean difference (WMD) for continuous outcomes and the relative risk (RR) for dichotomous outcomes. The former measure retains the original data units and the latter is a unitless ratio. An event rate ratio was estimated if a study reported hypoglycemic and hyperglycemic events per period of time. The estimates from each study were pooled using a random-effects model incorporating the between-study heterogeneity as well as the within-study heterogeneity. The extent of heterogeneity was assessed using the I^2 statistic. Interaction between subgroups was tested using an interaction test and meta-regression. A priori established subgroup analyses were based on the type of CGM (real-time versus non-real-time), loss to follow up, and adherence monitoring. To assess publication bias, the Task Force planned to inspect funnel plots visually and test their symmetry statistically using Egger's regression test.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The Clinical Guidelines Subcommittee of The Endocrine Society deemed continuous glucose monitoring (CGM) a priority area in need of practice guidelines and appointed a Task Force to formulate evidence-based recommendations.

Participants

The Endocrine Society appointed a Task Force of experts, a methodologist, and a medical writer.

Evidence

The Task Force followed the approach recommended by the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) workgroup, an international group with expertise in development and implementation of evidence-based guidelines. A detailed description of the grading scheme has been published elsewhere.

The Task Force used the best available research evidence that Task Force members identified and one commissioned systematic literature review

of randomized controlled trials of CGM use to inform some of the recommendations. The Task Force also used consistent language and graphical descriptions of both the strength of a recommendation and the quality of evidence. In terms of the strength of the recommendation, strong recommendations use the phrase "the Task Force recommends" and the number 1, and weak recommendations use the phrase "the Task Force suggests" and the number 2. The symbol +OOO denotes very low quality evidence; ++OO, low quality; +++O, moderate quality; and ++++, high quality. The Task Force has confidence that persons who receive care according to the strong recommendations will derive, on average, more good than harm. Weak recommendations require more careful consideration of the person's circumstances, values, and preferences to determine the best course of action. Linked to each recommendation is a description of the evidence and the values that panelists considered in making the recommendation. All of the Task Force's recommendations are expert opinions and are evidence based. Some of these opinions are based on stronger evidence than others. For strong recommendations with GRADE 1 evidence, the Task Force has made recommendations, and for weak recommendations with GRADE 2 evidence, the Task Force has made suggestions.

Consensus Process

One group meeting, several conference calls, and e-mail communications enabled consensus.

Rating Scheme for the Strength of the Recommendations

Strength of Recommendation

1- Indicates a strong recommendation and is associated with the phrase "The Task Force recommends."

2 - Denotes a weak recommendation and is associated with the phrase "The Task Force suggests."

Cost Analysis

The Task Force has considered the cost-benefit issues related to the use of continuous glucose monitoring (CGM) and feels that the clinical benefits justify the costs in a wide range of patients, but that these values may not be universally shared in some healthcare settings (e.g., those with resource-constrained settings, clinics unable to provide adequate support to patients and families). Individuals or health systems may disagree with the Task Force's relative valuation, and in these cases the recommendations may not apply. It may then be necessary to modify these recommendations accordingly.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Committees and members of The Endocrine Society, the Diabetes Technology Society, and the European Society of Endocrinology reviewed and commented on preliminary drafts of these guidelines.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is specifically stated for each recommendations (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of continuous glucose monitoring in pediatric and adult patients to improve glycemic control

Potential Harms

No significant adverse effects related to the device were reported in any of the trials. Data on the incidence of severe hypoglycemia, hyperglycemia, nocturnal hypoglycemia, or severe hyperglycemia were very sparse, poorly reported, and imprecise. The relative risk (RR) for hypoglycemia (based on number of patients suffering at least one episode of hypoglycemia as the unit of analysis) was 1.02 (95% CI, 0.3 to 3.45). Using the number of events as the unit of analysis, the rate ratio for hypoglycemia was 3.50 (95% CI, 1.07 to 11.44) and for hyperglycemia 1.42 (95% CI, 0.26 to 7.82).

Qualifying Statements

Qualifying Statements

- Clinical Practice Guidelines are developed to be of assistance to endocrinologists and other health care professionals by providing guidance and recommendations for particular areas of practice. The Guidelines should not be considered inclusive of all proper approaches or methods, or exclusive of others. The Guidelines cannot guarantee any specific outcome, nor do they establish a standard of care. The Guidelines are not intended to dictate the treatment of a particular patient. Treatment decisions must be made based on the independent judgment of health care providers and each patient's individual circumstances.
- The Endocrine Society makes no warranty, express or implied, regarding the Guidelines and specifically excludes any warranties of merchantability and fitness for a particular use or purpose. The Society shall not be liable for direct, indirect, special, incidental, or consequential damages related to the use of the information contained herein.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Patient Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Safety

Identifying Information and Availability

Bibliographic Source(s)

Klonoff DC, Buckingham B, Christiansen JS, Montori VM, Tamborlane WV, Vigersky RA, Wolpert H, Endocrine Society. Continuous glucose monitoring: an Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2011 Oct;96(10):2968-79. PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2011 Oct

Guideline Developer(s)

The Endocrine Society - Professional Association

Source(s) of Funding

The Endocrine Society

Guideline Committee

Continuous Glucose Monitoring Task Force

Composition of Group That Authored the Guideline

Task Force Members: David C. Klonoff (*Chair*); Bruce Buckingham; Jens S . Christiansen; Victor M. Montori; William V. Tamborlane; Robert A. Vigersky; and Howard Wolpert

Financial Disclosures/Conflicts of Interest

Financial Disclosures of the Task Force

David C. Klonoff, M.D., F.A.C.P. (chair) — Financial or Business/Organizational Interests: Bayer, C8 MediSensors, Insuline, LifeScan, Medtronic Diabetes, Roche; Significant Financial Interest or Leadership Position: Diabetes Technology Society

Bruce Buckingham, M.D. — Financial or Business/Organizational Interests: MedTronic MiniMed, LifeScan, Novo Nordisk, JDRF, UnoMedical; Significant Financial Interest or Leadership Position: none declared

Jens S. Christiansen, M.D., F.R.C.P.I., Dr.Med.Sci. — Financial or Business/Organizational Interests: Novo Nordisk, Roche; Significant Financial Interest or Leadership Position: European Society of Endocrinology

Victor M. Montori, M.D.* — Financial or Business/Organizational Interests: KER Unit (Mayo Clinic); Significant Financial Interest or Leadership Position: none declared

William V. Tamborlane, M.D. — Financial or Business/Organizational Interests: Medtronic Diabetes, Abbott Diabetes, Novo Nordisk, Eli Lilly, Macrogenics; Significant Financial Interest or Leadership Position: Novo Nordisk, Eli Lilly, Medtronic, Macrogenics

Robert A. Vigersky, M.D. — Financial or Business/Organizational Interests: Dexcom; Significant Financial Interest or Leadership Position: The Endocrine Society

Howard Wolpert, M.D. — Financial or Business/Organizational Interests: Insulet, Novo Nordisk, Roche; Significant Financial Interest or Leadership Position: Insulet

*Evidence-based reviews for this guideline were prepared under contract with The Endocrine Society.

Guideline Endorser(s)

Diabetes Technology Society - Disease Specific Society

European Society of Endocrinology - Medical Specialty Society

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from The Endocrine Society Web site .

Print copies: Available from The Endocrine Society, Phone: (301) 941.0210; Email: Societyservices@endo-society.org

Availability of Companion Documents

The following is available:

- Gandhi GY, Kovalaske M, Kudva Y, Walsh K, Elamin MB, Beers M, Coyle C, Goalen M, Murad MS, Erwin PJ, Corpus J, Montori VM, Murad MH. Efficacy of continuous glucose monitoring in improving glycemic control and reducing hypoglycemia: a systematic review and meta-analysis of randomized trials. J Diabetes Sci Technol. 5(4):952-965. Electronic copies: Available to subscribers from the Journal of Diabetes Science and Technology Web site .

Patient Resources

The following is available:

- Patient guide to continuous glucose monitoring. Chevy Chase (MD): The Hormone Foundation; 2011 Oct. 2 p. Electronic copies: Available from The Hormone Foundation Web site .

Print copies: Available from The Endocrine Society, Phone: (301) 941.0210; Email: Societyservices@endo-society.org

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on June 12, 2012. The information was verified by the guideline developer on June 22, 2012.

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